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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
TON, THAIAN N	
ART UNIT	PAPER NUMBER
1632	7

DATE MAILED: 08/07/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/846,456	ROSIER-MONTUS ET AL.	
	Examiner	Art Unit	
	Thaian N. Ton	1632	

-- The MAILING DATE of this communication app ars on the cover sheet with th correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-56 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-56 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-38, drawn to isolated nucleic acids, recombinant vectors and host cells, classified in class 435, subclass 320.1, 325+, 455.

II. Claims 39 and 40, drawn to non-human transgenic mammals, classified in class 800, subclass 3.

III. Claim 41, drawn to a method for screening a substance or molecule which modifies the transcription of the polynucleotide which is a constituent of the isolated nucleic acid, classified in class 435 subclass 4.

IV. Claim 42, drawn to a kit for screening *in vitro*, a candidate molecule or substance which modifies the transcription of a polypeptide of interest which is a constituent of the isolated nucleic acid comprising a host cell transformed with a nuclei acid and optionally, a means required for detecting the transcription of the polynucleotide of interest which is a constituent of the isolated nucleic acid, classified in class 435, subclass 4.

V. Claim 43, drawn to a method for screening *in vivo* a substance or molecule which modifies the transcription of a polynucleotide of interest which is a constituent of the isolated nucleic acid, classified in class 424, subclass 9.2.

VI. Claim 44, drawn to a kit or pack for screening *in vivo* at least one candidate molecule or substance which modifies the transcription of the polynucleotide of interest which is a constituent of the isolated nucleic acid, classified in class 424, subclass 9.2.

VII. Claim 45-50, drawn to an undisclosed substance which modifies the transcription of a polynucleotide of interest which is a constituent of the isolated nucleic acid, and pharmaceutical compositions, unclassifiable.

VIII. Claim 51, drawn to a method for detecting impairment of the transcription of the ABC1 gene in an individual comprising extracting the total mRNA from a biological material originating from the individual to be tested, quantifying the ABC1 messenger RNA present in the biological material, comparing the amount of ABC1 mRNA obtained from the biological sample with the amount of ABC1 mRNA expected in a normal individual, classified in class 435, subclass 4.

IX. Claim 52, drawn to a method for detecting an impairment of the transcription of the ABC1 gene in an individual comprising sequencing, classified in class 435, subclass 4.

X. Claim 53, drawn to a kit for detecting an impairment of the transcription of the ABC1 gene in an individual comprising the means for quantifying the ABC1 mRNA in a biological material originating from said individual, classified in class 435 subclass 4.

XI. Claim 54, drawn to a kit for detecting an impairment of the transcription of the ABC1 gene in an individual, comprising the means required for sequencing a polynucleotide located upstream of the transcription start site of the ABC1 gene in said individual, classified in class 435, subclass 4.

XII. Claim 55, drawn to a method for screening a molecule or substance which modifies the transcription of a polynucleotide of interest which is a constituent of an isolated nucleic acid by detection of complex formation, classified in class 435, subclass 4.

XIII. Claim 56, drawn to a kit or pack for screening a candidate molecule or substance which modifies the transcription of the polynucleotide of interest which is a constituent of the isolated nucleic acid comprising at least one isolated nucleic acid and optionally, the means required for detecting the complex formed between the candidate molecule or substance and said isolated nucleic acid, classified in class 435, subclass 4.

The inventions are distinct, each from the other because of the following reasons:

Invention I and II are to distinct products. The isolated nucleic acids of Invention I can be used to produce protein *in vitro*. The non-human transgenic

animals of Invention II can be used to observe gene function, or as models for disease or condition.

Inventions I and any of Inventions III, IV, VII, VIII, IX, XII, XIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid of Invention I can be used to produce protein *in vitro*.

Inventions I and any of Inventions V, VI, X, XI are mutually exclusive and independent. The isolated nucleic acids of Invention I are not required for the implementation of the methods for screening *in vivo* a substance or molecule which modifies the transcription of a polynucleotide of interest of Invention V, the kit or pack for screening *in vivo* of Invention VI, the kit for detecting an impairment of the transcription of the ABC1 gene in an individual comprising the means for quantifying the ABC1 mRNA in a biological material originating from said individual of Invention X and the kit for detecting an impairment of the transcription of the ABC1 gene in an individual, comprising the means required for sequencing a polynucleotide located upstream of the transcription start site of the ABC1 gene in said individual of Invention XI and vice versa.

Invention II and any of Inventions III, IV, VII-XIII are mutually exclusive and independent inventions. The non-human transgenic animals of Invention I are not required for the implementation of the method for screening a substance or molecule which modifies the transcription of the polynucleotide of Invention III, the kit for screening *in vitro* of Invention IV, the undisclosed substance which modifies the transcription of a polynucleotide of interest which is a constituent of the isolated nucleic acid, and pharmaceutical compositions of Invention VII, the method for detecting impairment of the transcription of the ABC1 gene in an individual comprising extracting the total mRNA of Invention VIII, the method for detecting impairment of the transcription of the ABC1 gene in an individual of Invention IX, the kit for detecting an impairment of the transcription of the ABC1 gene in an individual comprising the means for quantifying the ABC1 mRNA of Invention X, the kit for detecting an impairment of the transcription of the ABC1 gene in an individual, comprising the means required for sequencing a polynucleotide located upstream of the transcription start site of the ABC1 gene of Invention XI, the method for screening a molecule or substance which modifies the transcription of a polynucleotide of interest which is a constituent of an isolated nucleic acid by detection of complex formation of Invention XII and the kit or pack for screening a candidate molecule or substance which modifies the transcription of the polynucleotide of interest which is a constituent of the isolated nucleic acid comprising at least one isolated nucleic acid and optionally, the means required for

detecting the complex formed between the candidate molecule or substance and said isolated nucleic acid of Invention XIII, and vice versa.

Inventions II and either of Inventions V or VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the transgenic non-human mammals of Invention II can be used as models for disease or condition.

Invention III and any of Inventions IV-XIII are mutually exclusive and independent inventions. The method for screening a substance or molecule which modifies the transcription of the polynucleotide of Invention III is not required for the implementation of the kit for screening *in vitro* of Invention IV, the method for screening *in vivo* of Invention V, the kit or pack for screening *in vivo* of Invention VI, the undisclosed substance which modifies the transcription of a polynucleotide of interest which is a constituent of the isolated nucleic acid, and pharmaceutical compositions of Invention VII, the method for detecting impairment of the transcription of the ABC1 gene in an individual comprising extracting the total mRNA from a biological material originating from the individual to be tested of Invention VIII, the method for detecting impairment of the transcription of the ABC1 gene in an individual of Invention IX, the kit for detecting an impairment of

the transcription of the ABC1 gene in an individual comprising the means for quantifying the ABC1 mRNA of Invention X, the kit for detecting an impairment of the transcription of the ABC1 gene in an individual, comprising the means required for sequencing a polynucleotide located upstream of the transcription start site of the ABC1 gene of Invention XI, the method for screening a molecule or substance which modifies the transcription of a polynucleotide of interest which is a constituent of an isolated nucleic acid by detection of complex formation of Invention XII and the kit or pack for screening a candidate molecule or substance which modifies the transcription of the polynucleotide of interest which is a constituent of the isolated nucleic acid comprising at least one isolated nucleic acid and optionally, the means required for detecting the complex formed between the candidate molecule or substance and said isolated nucleic acid of Invention XIII, and vice versa. Furthermore, each of the methods requires a separate and materially different protocol.

Inventions IV and any of Inventions V-XIII are mutually exclusive and independent inventions. The kit for screening *in vitro* of Invention IV is not required for the implementation of the method for screening *in vivo* of Invention V, the kit or pack for screening *in vivo* of Invention VI, the undisclosed substance which modifies the transcription of a polynucleotide of interest which is a constituent of the isolated nucleic acid, and pharmaceutical compositions of Invention VII, the method for detecting impairment of the transcription of the

ABC1 gene in an individual comprising extracting the total mRNA from a biological material originating from the individual to be tested of Invention VIII, the method for detecting impairment of the transcription of the ABC1 gene in an individual of Invention IX, the kit for detecting an impairment of the transcription of the ABC1 gene in an individual comprising the means for quantifying the ABC1 mRNA of Invention X, the kit for detecting an impairment of the transcription of the ABC1 gene in an individual, comprising the means required for sequencing a polynucleotide located upstream of the transcription start site of the ABC1 gene of Invention XI, the method for screening a molecule or substance which modifies the transcription of a polynucleotide of interest which is a constituent of an isolated nucleic acid by detection of complex formation of Invention XII and the kit or pack for screening a candidate molecule or substance which modifies the transcription of the polynucleotide of interest which is a constituent of the isolated nucleic acid comprising at least one isolated nucleic acid and optionally, the means required for detecting the complex formed between the candidate molecule or substance and said isolated nucleic acid of Invention XIII, and vice versa.

Invention V and any of Inventions VI-XIII are mutually exclusive and independent. The method for screening *in vivo* of Invention V is not required for the kit or pack for screening *in vivo* of Invention VI, the undisclosed substance which modifies the transcription of a polynucleotide of interest which is a constituent of the isolated nucleic acid, and pharmaceutical compositions of

Invention VII, the method for detecting impairment of the transcription of the ABC1 gene in an individual comprising extracting the total mRNA from a biological material originating from the individual to be tested of Invention VIII, the method for detecting impairment of the transcription of the ABC1 gene in an individual of Invention IX, the kit for detecting an impairment of the transcription of the ABC1 gene in an individual comprising the means for quantifying the ABC1 mRNA of Invention X, the kit for detecting an impairment of the transcription of the ABC1 gene in an individual, comprising the means required for sequencing a polynucleotide located upstream of the transcription start site of the ABC1 gene of Invention XI, the method for screening a molecule or substance which modifies the transcription of a polynucleotide of interest which is a constituent of an isolated nucleic acid by detection of complex formation of Invention XII and the kit or pack for screening a candidate molecule or substance which modifies the transcription of the polynucleotide of interest which is a constituent of the isolated nucleic acid comprising at least one isolated nucleic acid and optionally, the means required for detecting the complex formed between the candidate molecule or substance and said isolated nucleic acid of Invention XIII, and vice versa. Furthermore, each of the methods requires a separate and materially different protocol.

Invention VI and any of Inventions VII-XIII are mutually exclusive and independent inventions. The kit or pack for screening *in vivo* of Invention VI is not required for the undisclosed substance which modifies the transcription of a

polynucleotide of interest which is a constituent of the isolated nucleic acid, and pharmaceutical compositions of Invention VII, the method for detecting impairment of the transcription of the ABC1 gene in an individual comprising extracting the total mRNA from a biological material originating from the individual to be tested of Invention VIII, the method for detecting impairment of the transcription of the ABC1 gene in an individual of Invention IX, the kit for detecting an impairment of the transcription of the ABC1 gene in an individual comprising the means for quantifying the ABC1 mRNA of Invention X, the kit for detecting an impairment of the transcription of the ABC1 gene in an individual, comprising the means required for sequencing a polynucleotide located upstream of the transcription start site of the ABC1 gene of Invention XI, the method for screening a molecule or substance which modifies the transcription of a polynucleotide of interest which is a constituent of an isolated nucleic acid by detection of complex formation of Invention XII and the kit or pack for screening a candidate molecule or substance which modifies the transcription of the polynucleotide of interest which is a constituent of the isolated nucleic acid comprising at least one isolated nucleic acid and optionally, the means required for detecting the complex formed between the candidate molecule or substance and said isolated nucleic acid of Invention XIII, and vice versa.

Invention VII and any of Inventions VIII-XIII are mutually exclusive and independent inventions. The undisclosed substance which modifies the

transcription of a polynucleotide of interest which is a constituent of the isolated nucleic acid, and pharmaceutical compositions of Invention VII is not required for the method for detecting impairment of the transcription of the ABC1 gene in an individual comprising extracting the total mRNA from a biological material originating from the individual to be tested of Invention VIII, the method for detecting impairment of the transcription of the ABC1 gene in an individual of Invention IX, the kit for detecting an impairment of the transcription of the ABC1 gene in an individual comprising the means for quantifying the ABC1 mRNA of Invention X, the kit for detecting an impairment of the transcription of the ABC1 gene in an individual, comprising the means required for sequencing a polynucleotide located upstream of the transcription start site of the ABC1 gene of Invention XI, the method for screening a molecule or substance which modifies the transcription of a polynucleotide of interest which is a constituent of an isolated nucleic acid by detection of complex formation of Invention XII and the kit or pack for screening a candidate molecule or substance which modifies the transcription of the polynucleotide of interest which is a constituent of the isolated nucleic acid comprising at least one isolated nucleic acid and optionally, the means required for detecting the complex formed between the candidate molecule or substance and said isolated nucleic acid of Invention XIII, and vice versa.

Invention VIII and any of Inventions IX-XIII are mutually exclusive and independent inventions. The method for detecting impairment of the transcription

of the ABC1 gene in an individual comprising extracting the total mRNA from a biological material originating from the individual to be tested of Invention VIII is not required for the implementation of the method for detecting impairment of the transcription of the ABC1 gene in an individual of Invention IX, the kit for detecting an impairment of the transcription of the ABC1 gene in an individual comprising the means for quantifying the ABC1 mRNA of Invention X, the kit for detecting an impairment of the transcription of the ABC1 gene in an individual, comprising the means required for sequencing a polynucleotide located upstream of the transcription start site of the ABC1 gene of Invention XI, the method for screening a molecule or substance which modifies the transcription of a polynucleotide of interest which is a constituent of an isolated nucleic acid by detection of complex formation of Invention XII and the kit or pack for screening a candidate molecule or substance which modifies the transcription of the polynucleotide of interest which is a constituent of the isolated nucleic acid comprising at least one isolated nucleic acid and optionally, the means required for detecting the complex formed between the candidate molecule or substance and said isolated nucleic acid of Invention XIII, and vice versa. Furthermore, each of the methods requires a separate and materially different protocol.

Invention IX and any of Inventions X-XIII are mutually exclusive and independent inventions. The method for detecting impairment of the transcription of the ABC1 gene in an individual of Invention IX is not required for the kit for

detecting an impairment of the transcription of the ABC1 gene in an individual comprising the means for quantifying the ABC1 mRNA of Invention X, the kit for detecting an impairment of the transcription of the ABC1 gene in an individual, comprising the means required for sequencing a polynucleotide located upstream of the transcription start site of the ABC1 gene of Invention XI, the method for screening a molecule or substance which modifies the transcription of a polynucleotide of interest which is a constituent of an isolated nucleic acid by detection of complex formation of Invention XII and the kit or pack for screening a candidate molecule or substance which modifies the transcription of the polynucleotide of interest which is a constituent of the isolated nucleic acid comprising at least one isolated nucleic acid and optionally, the means required for detecting the complex formed between the candidate molecule or substance and said isolated nucleic acid of Invention XIII, and vice versa. Furthermore, each of the methods requires a separate and materially different protocol.

Inventions X and any of Inventions XI-XIII are mutually exclusive and independent inventions. The kit for detecting an impairment of the transcription of the ABC1 gene in an individual comprising the means for quantifying the ABC1 mRNA of Invention X is not required for the kit for detecting an impairment of the transcription of the ABC1 gene in an individual, comprising the means required for sequencing a polynucleotide located upstream of the transcription start site of the ABC1 gene of Invention XI, the method for screening a molecule or substance which

modifies the transcription of a polynucleotide of interest which is a constituent of an isolated nucleic acid by detection of complex formation of Invention XII and the kit or pack for screening a candidate molecule or substance which modifies the transcription of the polynucleotide of interest which is a constituent of the isolated nucleic acid comprising at least one isolated nucleic acid and optionally, the means required for detecting the complex formed between the candidate molecule or substance and said isolated nucleic acid of Invention XIII, and vice versa.

Inventions XI and either of Inventions XII or XIII are mutually exclusive and independent inventions. The kit for detecting an impairment of the transcription of the ABC1 gene in an individual, comprising the means required for sequencing a polynucleotide located upstream of the transcription start site of the ABC1 gene of Invention XI is not required for the implementation of the method for screening a molecule or substance which modifies the transcription of a polynucleotide of interest which is a constituent of an isolated nucleic acid by detection of complex formation of Invention XII and the kit or pack for screening a candidate molecule or substance which modifies the transcription of the polynucleotide of interest which is a constituent of the isolated nucleic acid comprising at least one isolated nucleic acid and optionally, the means required for detecting the complex formed between the candidate molecule or substance and said isolated nucleic acid of Invention XIII, and vice versa.

Inventions XII and XIII are mutually exclusive and independent inventions. The method for screening a molecule or substance which modifies the transcription of a polynucleotide of interest which is a constituent of an isolated nucleic acid by detection of complex formation of Invention XII is not required for the kit or pack for screening a candidate molecule or substance which modifies the transcription of the polynucleotide of interest which is a constituent of the isolated nucleic acid comprising at least one isolated nucleic acid and optionally, the means required for detecting the complex formed between the candidate molecule or substance and said isolated nucleic acid of Invention XIII, and vice versa.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thaian N. Ton whose telephone number is (703) 305-1019. The examiner can normally be reached on Monday through Friday from 8:00 to 5:00 (Eastern Standard Time), with alternating Fridays off. Should the examiner be unavailable, inquiries should be directed to Deborah Reynolds, Supervisory Primary Examiner of Art Unit 1632, at (703) 305-4051. Any administrative or procedural questions should be directed to Patsy Zimmerman, Patent Analyst, at (703) 305-2758. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 308-8724.

Deborah Crouch

DEBORAH CROUCH
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